

Remarks

Following entry of this amendment, claims 30-41 are pending in the application. New claims 39-41 are added herein. Support for new claims 39 and 41 can be found throughout the specification, such as on pages 21-22. Support for new claim 40 can be found throughout the specification, for example on page 7, line 31 to page 8, line 8. Support for new claim 41 can be found throughout the specification, for example on page 22.

Applicants believe no new matter is added herein. Consideration of the pending claims is requested.

Restriction Requirement

Claims 30-38 were subject to a Restriction Requirement. In response, Applicants elect SEQ ID NO: 9, with traverse. Applicants expressly reserve the right to petition the restriction requirement.

The Office action alleges that SEQ ID NOs: 9-14 are structurally unrelated. Applicants strongly disagree with this assertion. The nucleotide sequences shown in SEQ ID NOs: 9-16 are the quinolone resistance determining region (QRDR) sequences from the *gyrA* gene of Enterobacteriaceae species. Relative to the *E. coli* sequences, the QRDR sequence corresponds to nucleotides 199 to 318 of the *gyrA* gene.

The claimed methods are directed to determining the quinolone resistance status of Enterobacteriaceae species. Simultaneous identification of the species and mutations leading to resistance can be determined using probes described in the specification (see for example, page 21, line 30 to page 22, line 2, and Tables 3 and 4, found on pages 21 and 22, respectively). Generally, susceptible strains will hybridize to the probe and resistance is detected by a one or more base pair mismatch. Exemplary probes that can be used to determine the quinolone resistance status, namely SEQ ID NOs: 25-33 (that correspond to 25 nucleotides of one of SEQ ID NOs: 1-9), are disclosed in specification in Table 4.

The specification discloses that the amino acid sequences of the QRDR polypeptides encoded by SEQ ID NOs: 9-16 are very related (and many are identical). The polypeptide encoded by SEQ ID NO: 9 is 100% identical to the polypeptides encoded by SEQ ID NO: 12, SEQ ID NO: 14 and SEQ ID NO: 16. The polypeptide encoded by SEQ ID NO: 9 differs by only one amino acid from the polypeptide encoded by SEQ ID NO: 10, SEQ ID NO: 11 and SEQ ID NO: 13. The polypeptide encoded by SEQ

ID NO: 9 differs by only two amino acids from SEQ ID NO: 15 (see page 18, lines 13-24). The nucleotide sequence set forth as SEQ ID NO: 9 (the E. coli sequence) is disclosed to be 93.3% identical to E. cloacae (SEQ ID NO: 12) and 80.8% identical to P. stuartii (SEQ ID NO: 15) (see page 17, lines 13-23). An alignment of QRDR sequences set forth as SEQ ID NOs: 9-16 is shown in Figure 2. Thus, the specification clearly discloses that these sequences are structurally related.

MPEP § 2434 states: “[n]ucleotide sequences encoding the same protein are not considered to be independent and distinct and will continue to be examined together.” Thus, it is clear that SEQ ID NO: 9 should be examined with SEQ ID NO: 12, SEQ ID NO: 14 and SEQ ID NO: 16. In addition, as the QRDR proteins encoded by SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 13 and SEQ ID NO: 15 differ from the polypeptide encoded by SEQ ID NO: 9 by at most two amino acids, Applicants submit that all of SEQ ID NOs: 9-14 should be examined a single application. It would not represent a burden on the Patent Office to examine the closely related sequences in a single patent application.

Applicants believe that these sequences should still be examined together in view of the sequence similarity of SEQ ID NOs: 9-14 at the nucleotide level,. MPEP § 2434 also states: “...the Commissioner has partially waived the requirements of 37 CFR 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, in most cases, up to 10 independent and distinct nucleotide sequences will be examined in a single application without restriction.”

Applicants respectfully request reconsideration and withdrawal of the restriction requirement. In the unlikely event that this restriction requirement is maintained, the Applicants expressly reserve the right to petition this restriction requirement.

Conclusion

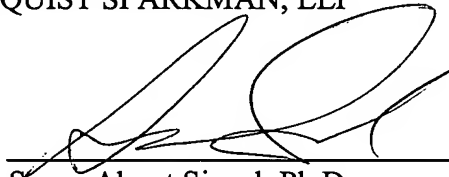
It is respectfully submitted that the amended claims submitted herewith should all be recombined and considered in the current case, and as such they are in a condition for substantive examination. If an additional restriction requirement is asserted, or if the present restriction requirement is maintained, the Examiner is formally requested to contact the undersigned prior to issuance of the next Office action, in order to arrange a telephonic interview. It is believed that a brief discussion of the merits of the present application may expedite prosecution. This request is being submitted under MPEP §713.01, which indicates that an interview may be arranged in advance by a written request.

Respectfully submitted,

KLARQUIST SPARKMAN, LLP

One World Trade Center, Suite 1600
121 S.W. Salmon Street
Portland, Oregon 97204
Telephone: (503) 595-5300
Facsimile: (503) 595-5301

By



Susan Alpert Siegel, Ph.D.
Registration No. 43,121